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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC.,	)	
Plaintiffs,	)	Civil Action No.
v.	)	
GLENMARK GENERICS INC., USA, GLENMARK GENERICS LTD., and GLENMARK PHARMACEUTICALS LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

For their Complaint against Defendants Glenmark Generics Inc., USA ("Glenmark Generics USA"), Glenmark Generics Ltd., and Glenmark Pharmaceuticals Ltd. ("Glenmark Ltd."; collectively, "Defendants"), Plaintiffs Teva Pharmaceutical Industries Ltd. ("Teva Ltd.")

and Teva Pharmaceuticals USA, Inc. ("Teva USA"; collectively, "Plaintiffs") allege as to their own acts, and on information and belief as to the acts of others, as follows:

THE PARTIES

1. Teva Ltd. is a corporation organized under the laws of Israel and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

2. Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.

3. On information and belief, Defendant Glenmark Generics USA is a Delaware corporation with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. On further information and belief, Defendant Glenmark Generics USA is the successor to Glenmark Pharmaceuticals Inc., USA. On further information and belief, Defendant Glenmark Generics USA is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey.

4. On information and belief, Defendant Glenmark Generics Ltd. is a corporation organized and existing under the laws of India with its principal place of business at Glenmark House, HDO-Corporate Building, Wing-A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai 400099, India. On further information and belief, Defendant Glenmark Generics Ltd., either directly or through its agents, is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey.

5. On information and belief, Defendant Glenmark Ltd. is a corporation organized and existing under the laws of India with its principal place of business at Glenmark House,

HDO-Corporate Building, Wing-A, B. D. Sawant Marg, Chakala, Off Western Express Highway, Andheri [East], Mumbai 400099, India. On further information and belief, Defendant Glenmark Ltd., either directly or through its agents, is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey. Defendant Glenmark Ltd. states on its website that it "has generic formulation and API business interests in over 85 countries across the world including the regulated markets of USA and Europe." See Glenmark Ltd. – Overview, at http://www.glenmarkpharma.com/about/index.html (attached hereto as Exhibit A). The website further states that Glenmark Ltd. "incorporated subsidiaries in the regulated markets of USA in FY 2003 and EU in FY 2005 and is making significant investments to build a strong API and generic formulations business in these markets." Id.

NATURE OF THE ACTION

6. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and seeking damages and injunctive relief under 35 U.S.C. §§ 271, 281–285.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over this controversy under 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction.

9. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants have systematic, purposeful, and continuous contacts in this District, Defendant

Glenmark Generics USA has a principal place of business in this District, and Defendants Glenmark Generics Ltd. and Glenmark Ltd. have availed themselves of the privilege of doing business in this District through their subsidiaries and agents. On further information and belief, Glenmark Generics USA is the successor to Glenmark Pharmaceuticals Inc., USA, who also had a principal place of business in this District.

10. Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b), (c), and (d).

FACTUAL BACKGROUND

The Patents in Suit

11. Teva Ltd. is the owner of all right, title and interest in United States Patent Nos. 6,699,997 ("the '997 Patent") and 7,126,008 ("the '008 Patent"; collectively, "the patents in suit") relating to, *inter alia*, processes for preparing a chemical compound known as carvedilol.

12. The '997 Patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on March 2, 2004 for an invention entitled "Carvedilol." A copy of the '997 Patent is attached as Exhibit B.

13. The '008 Patent was duly and legally issued by the PTO on October 24, 2006 for an invention entitled "Carvedilol." A copy of the '008 Patent is attached as Exhibit C.

GlaxoSmithKline's Exclusivity

14. Carvedilol is a pharmaceutical compound used in the treatment of congestive heart failure. It is the active pharmaceutical ingredient ("API") in the product sold by GlaxoSmithKline ("GSK") under the trade name COREG®. COREG® is included in the United States Food and Drug Administration's ("FDA") list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs

listed in the Orange Book may be used as the basis of a later applicant's Abbreviated New Drug Application to obtain approval of the applicant's generic drug product under 21 U.S.C. § 355(j).

15. The carvedilol compound is disclosed and claimed in U.S. Patent No. 4,503,067 ("the '067 Patent"), which is owned by GSK. The '067 Patent is listed in the FDA's Orange Book in association with COREG®. The '067 Patent expired on March 5, 2007.

16. Pursuant to 21 U.S.C. § 355a, GlaxoSmithKline was awarded a six-month period of pediatric exclusivity following the expiration of the '067 Patent. GlaxoSmithKline's pediatric exclusivity period ended on September 5, 2007. Pursuant to this exclusivity, the FDA could not grant final approval to any Abbreviated New Drug Application ("ANDA") holders for carvedilol during that period. After this period ended, the FDA began granting final approval to ANDA holders beginning immediately upon expiration of GSK's pediatric exclusivity period.

Defendants' Infringement of the Patents in Suit

17. On information and belief, Defendants submitted ANDA No. 78-251 to the FDA, requesting approval to market a generic version of COREG® in 3.125, 6.25, 12.5, and 25 mg dosage strengths.

18. On information and belief, Defendants received final approval of their ANDA from the FDA on September 5, 2007 and are able to market, offer for sale, and sell generic carvedilol tablets in the United States.

19. Under the Hatch-Waxman Act, ANDA holders must provide detailed information to the FDA about how the API to be used in their proposed generic products will be made. ANDA holders may make the API themselves or, instead, may purchase the API from a supplier. When an ANDA holder intends to purchase API from a supplier to use in the proposed product,

the ANDA holder may reference a Drug Master File ("DMF") submitted to the FDA by that supplier, instead of providing process information in the ANDA.

20. On information and belief, Defendants purchase carvedilol API from a third party DMF holder to use in the manufacture of their generic carvedilol tablets ("Defendants' tablets").

21. On information and belief, Defendants engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic carvedilol tablets in the United States. Defendants have identified generic carvedilol tablets among their product offerings in publicly-available documents.

22. On information and belief, Defendants are engaging in the activities described in Paragraph 21 prior to the expiration of the patents in suit.

23. On information and belief, Defendants' tablets include carvedilol API that infringes or will infringe one or more claims of the patents in suit, and/or that is or will be made by a process that infringes one or more claims of the patents in suit, and/or that is imported, sold, offered for sale, or used in the United States after being made by a process that infringes one or more claims of the patents in suit.

24. As a direct and proximate consequence of the infringement by Defendants, Plaintiffs will be injured in their business and property rights unless the infringement is enjoined by the Court, and will suffer injury for which they are entitled to relief.

COUNT I

Infringement of the '997 Patent

25. Plaintiffs repeat and reallege Paragraphs 1 through 24 of the Complaint as if fully set forth herein.

26. On information and belief, the importation, manufacture, use, sale and/or offer for sale by Defendants of their carvedilol tablets pursuant to ANDA No. 78-251 infringes, either literally or under the doctrine of equivalents, claims 1, 2, 3, 7, and 8 of the '997 Patent, or contributes to or induces such infringement, under 35 U.S.C. § 271.

COUNT 2

Infringement of the '008 Patent

27. Plaintiffs repeat and reallege Paragraphs 1 through 26 of the Complaint as if fully set forth herein.

28. On information and belief, the importation, manufacture, use, sale and/or offer for sale by Defendants of their carvedilol tablets pursuant to ANDA No. 78-251 infringes, either literally or under the doctrine of equivalents, claim 2 of the '008 Patent, or contributes to or induces such infringement, under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Teva Ltd. and Teva USA respectfully request a judgment from the Court:

1. Declaring that claims 1, 2, 3, 7, and 8 of the '997 Patent and claim 2 of the '008 Patent are valid and enforceable;

2. Declaring that Defendants infringe, either literally or under the doctrine of equivalents, claims 1, 2, 3, 7, and 8 of the '997 Patent and claim 2 of the '008 Patent, or contribute to or induce such infringement, under 35 U.S.C. § 271;

3. Declaring that Defendants' infringement is willful and that this is an exceptional case under 35 U.S.C. § 285 entitling Plaintiffs to recover treble damages and attorneys fees;

4. Permanently enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the '997 and '008 Patents;

5. Awarding Plaintiffs damages adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty;

6. Awarding Plaintiffs their attorneys' fees, costs, and expenses; and

7. Awarding Plaintiffs such other relief that the Court deems proper, just and equitable.

Dated: August 29, 2008

LITE DEPALMA GREENBERG & RIVAS, LLC

/s/ Michael E. Patunas

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Plaintiffs, by their attorneys, hereby certify that the matter in controversy is also the subject of the following actions:

Caption	**Docket No./Court**
Teva Pharmaceutical Industries Ltd., et al. v. Apotex, Inc., et al.	07-4897(GEB)/D.N.J.
Teva Pharmaceuticals Industries, Ltd, et al v. Zydus Pharmaceuticals, Inc., et al	07-4942(GEB)/D.N.J

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: August 29, 2008

LITE DEPALMA GREENBERG & RIVAS, LLC

/s/ Michael E. Patunas

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